Press Release

Göteborg December 14, 2022

IRLAB reports Last Patient Last Visit ("LPLV") achieved in Phase IIb clinical study of mesdopetam in PD-LIDs with top-line results anticipated mid-January 2023

Gothenburg, Sweden, December 14, 2022 – IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB A), a company discovering and developing novel treatments for the most troublesome symptoms of Parkinson's disease, today announced that the final patient has completed the treatment period and follow-up visit in the Phase IIb study of mesdopetam in levodopa-induced dyskinesia in people with Parkinson's disease (PD-LIDs). The top-line results are expected to be reported in mid-January 2023.

"Last patient last visit is an important milestone as it confirms that we have now successfully completed the treatment period in this clinical study. Final data collection will now be performed, and the database will be locked. This is then followed by the pre-specified statistical analyses, and we expect to report top-line results in mid-January," said Nicholas Waters, EVP and Head of R&D, IRLAB.

Mesdopetam, an oral dopamine D3 antagonist, is being developed in partnership with Ipsen as a treatment for Parkinson's disease levodopa-induced dyskinesias (PD-LIDs), a severe form of troublesome involuntary movements commonly occurring in Parkinson's disease. The Phase IIb study of mesdopetam is a randomized, double-blind, placebo-controlled study with the aim of evaluating the efficacy, safety and, optimal dose of mesdopetam in people with PD-LIDs. The study randomized 156 patients distributed across four groups, three dose levels of mesdopetam and a placebo group with approximately 40 patients in each group with a treatment period of three months. The study was conducted at 46 study sites in Europe, Israel and in the US.

"The final stages of this important trial, for what could be a major breakthrough in treating this severe unmet need in Parkinson's disease are now underway. I would like to thank the dedicated team for their constant hard work and continued diligence to ensure we report this data as soon as possible," said Richard Godfrey, Chief Executive Officer, IRLAB.

The global specialty pharma company Ipsen holds the exclusive right for further clinical development and commercialization of the mesdopetam program in PD-LIDs and potentially other indications.

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About Phase IIb study with mesdopetam

The Phase IIb study with mesdopetam is a randomized, double-blind, placebo-controlled study with the aim of evaluating the efficacy, safety and optimal dose of mesdopetam in people with Parkinson's disease affected by levodopa-induced dyskinesias (LIDs). The primary endpoint is change in daily hours of ON-time without troublesome dyskinesia ("good ON"-time) as assessed with 24-hour patient home diaries. The study has randomized 156 patients distributed across four groups, three dose levels of mesdopetam and a placebo group with approximately 40 patients in each group with a treatment period of three months. The study is conducted at 46 study sites in Europe, Israel and in the US. More information can be found on clinicaltrials.gov: NCT04435431, and EudraCT number: 2020-002010-41.

About mesdopetam

Mesdopetam (IRL790) is an oral dopamine D3-receptor antagonist being developed for the treatment of levodopa-induced dyskinesias (LIDs), a severe form of troublesome involuntary movements commonly occurring in Parkinson's disease. Mesdopetam also has potential in treating Parkinson's disease Psychosis (PD-P). In clinical studies, mesdopetam reduces time spent with troublesome dyskinesia and thereby increases daily "good ON"-time in patients with Parkinson's disease. Preclinical studies show that mesdopetam is a potent and efficacious antidyskinetic, and that mesdopetam also has the potential to prevent the development of dyskinesia. In 2021, Ipsen, a specialty pharma company, acquired exclusive global rights to the development and commercialization of mesdopetam.

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About IRLAB

IRLAB discovers and develops novel treatments of Parkinson's disease and other CNS disorders. The company's most advanced drug candidates, mesdopetam (IRL790) and pirepemat (IRL752), are in Phase IIb and are designed to treat some of the most difficult symptoms related to Parkinson's . In 2021, Ipsen, a specialty pharma company, acquired exclusive global rights to the development and commercialization of mesdopetam.

IRLAB has discovered and generated all its drug candidates and continues to discover innovative drug candidates for the treatment of CNS disorders through its proprietary systems biology-based Integrative Screening Process (ISP) research platform. In addition to IRLAB's strong clinical pipeline, the company is also progressing two preclinical programs, IRL942 and IRL757, towards Phase I studies. IRLAB is listed on Nasdaq Stockholm. More information on www.irlab.se.

Attachments

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